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vascularization therapy set forth in Applicants' claims 1-5 of the present invention or increasing the number of newly formed blood vessels.

The Examiner is correct that Ritter does not disclose a therapeutic composition including carbonated warm water having a CO₂ concentration of at least 700 ppm. In fact, the Ritter specification does not even mention warm carbonated water or carbon dioxide concentration and the temperature thereof. Accordingly, Ritter does not disclose or suggest Applicants' claimed vascularization therapy.

Rejection under 35 U.S.C. §102(b)

Applicants' Independent claim 1 is directed to a vascularization therapy having a combination of steps, including performing a vascularization treatment which increases the number of newly formed blood vessels of an affected site, the affected site of a peripheral blood vessel being immersed in carbonated warm water having a carbon dioxide concentration of at least 700 ppm and a temperature of 33-42°C. In independent claim 2, the number of newly formed blood vessels is increased by at least 1.5 times; in independent claim 3, by at least 1.1 times.

Nishimura does not disclose the vascularization therapy set forth in Applicants' independent claims. Nishimura does not even disclose immersing the affected site of a peripheral blood vessel in warm carbonated water having a carbon dioxide concentration of at least 700 ppm and a temperature of 33-42°C. Rather, Nishimura discloses immersing healthy males in carbonated warm water. It is, therefore, difficult to conclude that the Nishimura method is intended for use in vascularization therapy, as in Applicants' claimed invention. In any case, intensive and detailed studies would need to be performed in order to assess, select,

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reject, or apply the results of Nishimura for use in any therapy, let alone Applicants' claimed vascularization therapy.

Nishimura does not mention anything about vascularization as described in Applicants' claims 1-5. As correctly noted in the Office Action, the term "vascularization" as used in the claims refers to the "formation of new blood vessels," whereas the term "vasodilation" refers to the widening of blood vessels resulting from relaxation of the muscular wall of the vessels. What widens is actually the diameter of the interior (the lumen) of the vessel.

It is true that Nishimura discloses immersing a subject's right forearm in CO₂-rich water (1000 ppm) that was maintained at a temperature of 34°C and reports an increase in cutaneous blood flow, possibly due to cutaneous vasodilation as a result of the immersion. However, this "increase in cutaneous blood flow due to cutaneous vasodilation" has nothing to do with the "formation of new blood vessels". The above-described physiological effects are clearly distinct from each other, and Nishimura presents no objective evidence to link the two. This is also obvious from the fact that Nishimura does not use the term "vascularization" or mention anything about the "formation of new blood vessels". In fact, the final Office Action appears to mistakenly quote Nishimura, which actually reads, "In CO₂ bathing, increased cutaneous blood flow due to cutaneous vasodilation may facilitate **heat transfer from the body to water**" (Nishimura at page 340, second column, lines 12-14). Again, this is unrelated to the "formation of new blood vessels."

In addition, Applicant wish to point out that the "intended use" provisions of 35 U.S.C. § 112, sixth paragraph, discussed on page 3 of the

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Office Action, apply only to means-plus-function claims, whereas the present invention is directed to a vascularization therapy, not the "means-for" language of §112, sixth paragraph. Applicants' claims 1-5 are rejected under 35 U.S.C. §102 (b) based on Nishimura, not 35 U.S.C. §112, sixth paragraph.

In summary, Nishimura does not disclose the vascularization therapy set forth in Applicants' claims 1-5, nor can any intention be gleaned from Nishimura to use its technique in such a therapy. Much detailed work would clearly be needed before that could happen, even if there were such an intention. As can be seen, Nishimura does not anticipate Applicants' claims 1-5. Withdrawal of the rejection of claim 1-5 is, therefore, respectfully requested.

Rejection under 35 U.S.C. §103

As detailed in the previous response, Ritter does not mention carbonated warm water or carbon dioxide concentration and the temperature thereof at all in their specification, and thus Ritter does not teach or even suggest a vascularization therapy which involves the immersion of the affected site of a peripheral blood vessel in carbonated warm water having a carbon dioxide concentration of at least 700 ppm and a temperature of 33 to 42°C. This is also evident from the above quotation from the Office Action which does not recite carbonated warm water or carbon dioxide concentration and the temperature thereof at all from Ritter. In other words, Applicants fail to see anything in common between Ritter and the present invention. The part in Ritter (column 1, lines 19-22); i.e. "Essentially, all wound healing involves the repair of replacement of damaged tissues including but not limited to

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skin, muscle, neurologic tissues, bone, soft tissue, internal organs or vascular tissue", which the Office Action is using as the basis of an assertion that Ritter encompasses the "vascularization therapy" as claimed, is merely a statement made by Ritter. If Ritter encompasses the "vascularization therapy" as claimed in the present invention, all the therapeutic compositions invented after Ritter must have been anticipated and/or suggested by Ritter, which is clearly not the case. In other words, Ritter does not encompass "vascularization therapy" recited in the Claims of the present invention.

In addition, as noted above, the work of Nishimura does not appear to be intended for a therapy directly, and much more intensive work needs to be done from Nishimura to achieve Applicants' claimed invention. What is more, Nishimura work simply reports that immersing the right forearm of a subject in CO₂-rich water (1000 ppm) that was maintained at a temperature of 34 DC results in an increase in cutaneous blood flow, and an elevation of the score on thermal sensation. These physiological effects (i.e., an increase in cutaneous blood flow, cutaneous vasodilation, and elevation of the score on thermal sensation) are clearly different from the Applicants' claimed effect of increasing the number of newly formed blood vessels (vascularization). Any connection between the two is not supported by objective evidence in Nishimura or the Office Action. An Examiner's affidavit is requested. Absent a factual basis in the record, there appears to be no basis for concatenating the two references.

Since neither Nishimura nor Ritter discloses or suggests Applicants' claimed vascularization therapy, the combination of Ritter and Nishimura

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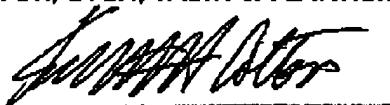
would not have rendered obvious Applicants' claimed invention. Withdrawal of the rejection of claims 1-9 under 35 U.S.C. §103(a) over Ritter in view of Nishimura is, therefore, respectfully requested.

Applicants hereby request a three-month extension of time in which to file this reply. The Commissioner is hereby authorized to charge the \$1100 extension fee to Deposit Account No. 06-1135 and is further authorized to charge any omitted fee required, including application processing, extension, and extra claims fees, to said Deposit Account.

Respectfully submitted,

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